

From: Temple, Anthony [MCCUS]
To: Mankad, Hiral [MCCUS]
Subject: RE: Standby Statement for Children's Motrin and Stevens Johnson Syndrome/Toxic Epidermal Necrolysis
Date: 03/26/2003 10:40:39 (GMT-05:00)

The difficulty is that we are now being sued. We were not in 2002.

Anthony R. Temple, MD
Vice-President, Medical Affairs
McNeil Consumer & Specialty Pharmaceuticals
Ft. Washington, PA 19034
215-273-7763

-----Original Message-----

From: Mankad, Hiral [MCCUS]
Sent: Wednesday, March 26, 2003 10:07 AM
To: Temple, Anthony [MCCUS]
Subject: RE: Standby Statement for Children's Motrin and Stevens Johnson Syndrome/Toxic Epidermal Necrolysis

Tony,

This was a standby statement that was approved in April of 2002 related to this same case. This statement was reviewed by the copy label committee (Tiziana, Paula & John Beidler) yesterday.

Hiral

-----Original Message-----

From: Temple, Anthony [MCCUS]
Sent: Wednesday, March 26, 2003 9:37 AM
To: Mankad, Hiral [MCCUS]
Subject: RE: Standby Statement for Children's Motrin and Stevens Johnson Syndrome/Toxic Epidermal Necrolysis

Has this been cleared with John Kim?? Who else reviewed? See sentence of concern below.

Anthony R. Temple, MD
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-----Original Message-----

From: Mankad, Hiral [MCCUS]
Sent: Wednesday, March 26, 2003 9:07 AM
To: Cullen, Jennifer [MCCUS]; Hoefling, Elizabeth [MCCUS]; Hussar, Suzanne [MCCUS]; Knight, Suzanne [MCCUS]; Kobylinski, Erica [MCCUS]; Kohutka, Danielle [MCCUS]; Mankad, Hiral [MCCUS]; Maresca, Christopher [MCCUS]; Miller, Joseph [MCCUS]; Rubincam, Michele [MCCUS]; Sabol, Pamela [MCCUS]; Segraves, Susan [MCCUS]; Marino, Gerri [MCCUS]; Matthews, Patricia [MCCUS]; Donohue, Pat [MCCUS]; Tramo, Danalynn [MCCUS]
Cc: Fox, Tiziana [MCCUS]; Ross, Stacey [MCCUS]; Williams, Tiffany [MCCUS]; Mortensen, Mary Ellen [MCCUS]; Baylor-Henry, Minnie [MCCUS]; Temple, Anthony [MCCUS]
Subject: Standby Statement for Children's Motrin and Stevens Johnson Syndrome/Toxic Epidermal Necrolysis

FYI, attached please find a standby statement to respond to any questions we receive regarding the legal case involving Children's Motrin and Stevens Johnson Syndrome/Toxic

MOT00007451.1

Epidermal Necrolysis.

Standby Statement: Report of TENS associated with Children's Motrin
3/26/03

McNeil Consumer & Specialty Pharmaceuticals is aware of a report of a 9-year old girl from California who has been diagnosed with Stevens-Johnson syndrome or toxic epidermal necrolysis allegedly associated with the use of Children's Motrin*. As the manufacturer of Motrin* ibuprofen products, we are deeply concerned about all matters relating to our products and are investigating this incident.

Stevens Johnson Syndrome and toxic epidermal necrolysis are serious skin reactions that are often associated with the use of medications. There are several medications that are associated with these skin reactions, including ibuprofen, the active ingredient in Children's Motrin products.¹

The labeling for prescription Motrin products indicates that Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported with the use of ibuprofen. However, reports of this reaction are extremely rare.

Reference:

1. Rumsfeld JA, West DP. Drug-induced skin disorders. In: Pharmacotherapy a Pathophysiologic Approach, 2nd ed. Norwalk, CT: Appleton & Lange, 1993:1387-1413.

If you have any questions, please feel free to contact me.

Thanks.
Hiral

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MOT00007451.2